DEC 1 1 2012

510(k) Summary: K122158

The following 510k Summary is provided in accordance with the requirements of 21 CFR 807.92.

1. Device Name and Classification

Device Trade Name:	PBP Total Hip System
Device:	Artificial Total Hip Replacement
Regulation Number and Description:	888.3358 - Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis 888.3350 - Hip joint metal/polymer semi-constrained cemented prosthesis) 888.3353 – Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Device Class:	II
Product Codes:	LPH - prosthesis, hip, semi-constrained, metal/polymer, porous uncemented JDI - prosthesis, hip, semi-constrained, metal/polymer, cemented OQG - hip prosthesis, semi-constrained, cemented, metal/polymer, + additive, porous, uncemented OQH - hip, semi-constrained, cemented, metal/polymer + additive, cemented MEH (hip, semi-constrained, uncemented, metal/polymer, non-porous, calcium-phosphate) LZO (Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis) OQI - hip, semi-constrained, cemented, metal/ceramic/polymer + additive, porous uncemented
Advisory Panel:	Orthopedic

2. Address and Registration

Submitter's Name:	Pipeline Biomedical Products, LLC
Address:	3 Wing Drive Suite 102 Cedar Knolls, NJ 07927
Contact Person:	Robert C. Cohen
Telephone Number:	(973) 267-8800
Fax Number:	(973) 267-8810

K122158

Date Summary Prepared: December 5, 2012
Establishment Registration Number: Not yet registered

3. Purpose of Submission

The purpose of this submission is to obtain 510k clearance for the PBP Total Hip System, a new device system for Pipeline Biomedical Products, LLC.

4. Identification of Legally Marketed Device to which Submitter Claims Equivalence

The subject PBP Total Hip System by Pipeline Biomedical Products is substantially equivalent to the predicate devices as outlined in the following table.

Table 1: Predicate Devices

Device Name	Company	510(k) Number	Clearance Date
Pipeline Total Hip System	Pipeline Orthopedics	K112802	3/9/2012
Tritanium® Peri-Apatite Acetabular Shell System	Howmedica Osteonics	K101072 K971206	4/11/2011 2/11/1998
Biolox *delta* Ceramic Femoral Head	Zimmer	K071535	11/19/2007

5. Device Description

The PBP Total Hip System is an artificial hip replacement system. The system includes femoral stems, femoral heads, acetabular shells, acetabular liners, acetabular bone screws and dome hole covers (occluders) for the holes in the acetabular shells.

The PBP Femoral Stems are forged titanium alloy and feature a proximal roughened surface (plasma-sprayed CP Titanium), a polished tapered neck, a flat tapered geometry with reduced A/P width (wedge design), and a contoured distal tip and reduced lateral shoulder. The PBP Femoral Stems come in a range of sizes, and are offered in two offset neck options per size.

The PBP Femoral Heads are available in a polished cobalt chromium alloy or a high purity alumina oxide ceramic compound (Biolox® *delta*). The heads come in a range of diameters and extension options. The variety of head and stem sizes and offsets accommodates differences in patient anatomy.

The PBP PST™ (Porous Structured Technology) Acetabular Shells are manufactured from titanium alloy and feature a porous structured surface or an HA porous structured surface. The shells feature a dome hole, are available with or without a cluster screw hole pattern for supplemental bone screw fixation, and come in a range of outer diameter sizes. The porous structured surface provides biologic fixation.

K122158

The PBP Acetabular Liners are manufactured from standard UHMWPE, or from highly crosslinked Vitamin E UHMWPE (XLVE™). The liners are mechanically assembled to the mating shells via engagement of the tightly toleranced liner taper and shell bore. The liners are available in a range of sizes and in neutral, high wall, and offset versions.

Optional components include a threaded acetabular dome hole occluder and acetabular bone screws, all manufactured from titanium alloy.

6. Intended Use

The PBP Total Hip System is indicated for use in skeletally mature individuals undergoing surgery for total hip replacement due to:

- A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, avascular necrosis, or congenital hip dysplasia;
- Acute traumatic fracture of the femoral head or neck;
- Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty or total hip replacement.

The PBP Total Hip System hip stems and porous structured acetabular shells are intended for cementless or cemented fixation. The porous structured surface provides biological fixation when used in a cementless application.

The PBP Total Hip System HA porous structured acetabular shells are intended for cementless fixation. The HA porous structured surface provides biological fixation.

7. Comparison of Technological Characteristics

The PBP Total Hip System is manufactured from the same materials as the predicate device systems. In addition, the components are packaged, and sterilized using similar processes. The subject Total Hip System is substantially equivalent to the predicates based on comparisons of intended use, design features and technological characteristics.

8. Performance Testing

The following performance tests were provided to demonstrate substantial equivalence:

- Biocompatibility testing for the highly crosslinked Vitamin E Polyethylene:
  - Cytotoxicity, 10993-5
  - Maximization/Sensitization, 10993-10
  - Intracutaneous, 10993-10
  - Acute Systemic Toxicity, 10993-11
  - Sub-acute/Subchronic Systemic Toxicity, 10993-11
  - Genotoxicity, 10993-3
  - Muscle Implantation, 10993-6.
- Wear testing:
  - Testing was conducted on 28 mm, 36mm and 40mm inner diameter highly crosslinked Vitamin E poly liners, that had been EO-sterilized and accelerated aged in

K122458

accordance with ASTM F2003, and subject to wear testing in accordance with ISO 14242, using a standard walking gait cycle as specified by ISO 14242-1.

- Bidirectional pin-on-disc abrasive wear testing was also conducted to compare the wear rates of the highly-crosslinked Vitamin E poly material to conventional (standard) gamma sterilized poly under clean and abrasive conditions. The wear reduction for the Vitamin E poly over conventional poly is 35% (7.7 vs 5 mg/Mc) in clean serum and 58% (8.3 vs 3.5 mg/Mc) in an abrasive environment.

- Wear particle characterization was conducted.
- The highly-crosslinked Vitamin E Polyethylene underwent exhaustive extraction testing using both polar and non-polar solvents, with GCMS and LCMS analysis to determine all volatile, semi-volatile, and non-volatile extracts. The results were compared to a predicate material to demonstrate that no new radiation degradation products are released by the material.
- Highly-crosslinked Vitamin E Polyethylene liners underwent oxidation analysis per ASTM F2102-06 after accelerated aging per ASTM F2003, wear testing, and exhaustive extraction. The analysis was also conducted on gamma-sterilized GUR 1020 (standard poly) reference material for comparison. The highly crosslinked Vitamin E poly exhibited lower oxidation indices than the standard poly, demonstrating higher resistance to oxidation: mean surface oxidation index was 0.017 for Vitamin E and 0.097 for standard poly; maximum oxidation index was 0.029 for Vitamin E and 0.248 for standard poly; and bulk oxidation index was 0.009 for Vitamin E and 0.036 for standard poly.
- Highly-crosslinked Vitamin E Polyethylene liners were evaluated by polarized light microscopy and SEM analysis of freeze fractured surfaces, after accelerated aging per ASTM F2003 and wear testing, to demonstrate that the subject material has equivalent consolidation to a predicate material.
- Liner Assembly/Disassembly Testing: Testing of the worst case size Pipeline Hip System highly crosslinked Vitamin E poly acetabular liner and worst case size conventional poly liner were tested for push-out, lever out torque, and axial torque.
- Hip Stem Fatigue Testing was conducted for the worst case (smallest) hip stem according to the method described in ISO 7206-4:2010, Implants for surgery-Partial and total hip joint prostheses, Determination of Endurance Properties and Performance of Stemmed Femoral Components.
- Stem Neck Fatigue Testing of the worst-case size was conducted according to the methods described in ISO 7206-6:1992 Implants for surgery-Partial and total hip joint prostheses-Part 6 and ASTM F2068-03 Standard Specification for Femoral Prostheses – Metallic Implants.
- Pull off testing was conducted on the metal and ceramic femoral heads.
- Burst Strength testing was conducted on Biolox *delta* Femoral Heads according to ISO 7206-10.
- An analysis was conducted of the typical and worst case ranges of motion permitted by the designs of various liner size/style, head size/style, and stem size/style combinations. The ROM was reported for flexion/extension, abduction/adduction, and internal/external rotation per ISO 21535.

K122158

- Bone screw testing was conducted in accordance with ASTM F543-07, Standard Specification and Test Methods for Metallic Medical Bone Screws, for torsion (torque to failure) and screw pull-out (pull-out to failure).
- Characterization in accordance with relevant aspects of "Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement," was completed for: 1) Acetabular Shell – PST Surface; 2) Acetabular Shell – HA PST Surface; 3) Hip Stem – Plasma-Spray Titanium Coating.
- Characterization in accordance with relevant aspects of "Guidance Document for the Preparation of Premarket Notifications for Ceramic Ball HIP Systems" was completed for the ceramic femoral heads.
- The porous structured surface was evaluated in a transcortical canine model to assess the biological response, using histological and mechanical evaluations, at intervals up to 12 weeks.

9. Conclusions

The subject PBP Total Hip System shares the same indications for use as the predicate hip system, and a comparison of technological characteristics supported by performance testing demonstrates the Substantial Equivalence of the PBP Total Hip System to the predicate hip systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

December 11, 2012

Pipeline Biomedical Products, Llc
% Mr. Terry Powell
Senior Project Manager
901 King Street, Suite 200
Alexandria, Virginia 22314

Re: K122158
Trade/Device Name: PBP Total Hip System
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis.
Regulatory Class: Class II
Product Code: OQI, LZO, MEH, OQH, OQG, JDI, LPH
Dated: November 14, 2012
Received: November 19, 2012

Dear Terry Powell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin L. Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K122158

Device Name: PBP Total Hip System

Indications for Use:

The PBP Total Hip System is indicated for use in skeletally mature individuals undergoing surgery for total hip replacement due to:

- A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, avascular necrosis, or congenital hip dysplasia;
- Acute traumatic fracture of the femoral head or neck;
- Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty; surface replacement arthroplasty or total hip replacement.

The PBP Total Hip System hip stems and porous structured acetabular shells are intended for cementless or cemented fixation. The porous structured surface provides biological fixation when used in a cementless application.

The PBP Total Hip System HA porous structured acetabular shells are intended for cementless fixation. The HA porous structured surface provides biological fixation.

Prescription Use ___X___ AND/OR (Part 21 CFR 801 Subpart D)

Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Krishna Arundi

Division of Orthopedic Devices

2012.12.10 16:53:59 -05'00'